

VIA HAND DELIVERY JANUARY 20, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ruben et al.

Atty. Docket No.: PF155P2

Application No.: 10/035,212

Group Art Unit: 1631

Filed: January 4, 2002

Examiner: M. Borin

For: Keratinocyte Growth Factor-2

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of a claim of the subject application, Attorneys for Applicants hereby direct the Examiner's attention to references AA-FG listed on the attached Form PTO/SB/08. A copy of each of references AA-FG is enclosed.

Applicants also wish to bring to the attention of the Examiner that SEQ ID NO:1 and the corresponding cDNA of this application are related to SEQ ID NO:40589 in copending U.S. Patent Application Serial No. 09/912,292. A legible copy of that portion of U.S. Patent Application Serial No. 09/912,292 which caused it to be listed on the attached revised form PTO/SB/08 is submitted herewith as reference AU.

The above information is presented so that the Patent and Trademark Office can determine any materiality thereof to the claimed invention. See 37 CFR § 1.104(a) concerning the PTO duty to consider and use any such information. It is respectfully requested that the information be considered during the prosecution of this application.

Identification of the listed reference(s) is not to be construed as an admission of any individual associated with the filing or prosecution of the subject application that such references are available as "prior art" against the subject application. Furthermore,

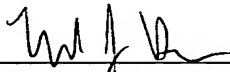
Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the subject application.

Applicants respectfully request that the Examiner review the listed references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b), since this information disclosure statement is being filed before the mailing date of a first Office Action on the merits, no fee is due in connection herewith. However, should the Patent Office determine otherwise, please charge the required fee to Human Genome Sciences, Inc., deposit account no. 08-3425.

Respectfully submitted,

Dated: January 20, 2004



Mark J. Hyman Reg. No. 46,789

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (240) 314-1224

MMW/MJH/KC/lcc



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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/035,212-Conf. #3494
				Filing Date	January 4, 2002
				First Named Inventor	Steven Ruben
				Art Unit	1631
				Examiner Name	M. Borin
Sheet	1	of	8	Attorney Docket Number	PF155P2

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	AA	5,194,596		Tischer et al.	03/16/1993	
	AB	5,350,836		Kopchick et al.	09/27/1994	
	AC	5,580,856		Prestrelski et al.	12/03/1996	
	AD	5,677,278		Gospodarowicz et al.	10/14/1997	
	AE	5,703,047		Wilson, S.E.	12/30/1997	
	AF	5,731,170		Rubin et al.	03/24/1998	
	AG	5,773,252		Greene et al.	Jun.1998	
	AH	5,773,586		Gospodarowicz et al.	06/30/1998	
	AI	5,814,605		Pierce et al.	09/29/1998	
	AJ	5,824,643		Pierce et al.	10/20/1998	
	AK	5,843,883		Gospodarowicz et al.	12/01/1998	
	AL	5,863,767		Gospodarowicz et al.	01/26/1999	
	AM	6,077,692		Ruben et al.	06/20/2000	
	AN	6,238,888 B1		Gentz et al.	05/29/2001	
	AO	6,599,879		Jimenez et al.	07/29/2003	
	AP	6,653,284		Gentz et al.	05/14/2001	
	AQ	2003/0129687		Ruben et al.	02/15/2003	
	AR	2003/0077695		Ruben et al.	04/24/2003	
	AS	2003/0119108		Laird et al.	06/26/2003	
	AT	2003/0186904		Ruben et al.	10/02/2003	
	AU	09/912,292		ROSEN et al.	NOT PUBLISHED	Pages 1-75 (pages 1 & 2 partially redacted); portion of Table 2; and SEQ ID NO:40589

FOREIGN PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office ³	Number ⁴	Kind Code ⁵ (if known)		
	AV	WO	90/08771		Rubin et al.	08/09/1990
	AW	WO	92/14480		Amgen, Inc.	09/03/1992
Examiner Signature					Date Considered	

¹ Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

² Unique citation designation number. ³ Applicant is to place a check mark here if English language Translation is attached.

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	AX	EP	0 518 697	A	Amgen, Inc.	12/16/1992		
	AY	WO	92/22304		Amgen, Inc.	12/23/1992		
	AZ	WO	93/21908		Amgen, Inc.	11/11/1993		
	BA	EP	0 619 370 A1	A	Amgen, Inc.	10/12/1994		
	BB	EP	0 619 115	A	Amgen, Inc.	10/12/1994		
	BC	WO	94/22427		Amgen, Inc.	10/13/1994		
	BD	WO	94/23032		Amgen, Inc.	10/13/1994		
	BE	WO	95/01434		Chiron Inc.	01/12/1995		
	BF	WO	95/03831		Prizm Pharmaceuticals, Inc	02/09/1995		
	BG	WO	95/24928 A3		Sumitomo Pharmaceuticals Co., Ltd.	09/21/1995		
	BH	WO	95/24928		Sumitomo Pharmaceuticals Co., Ltd.	09/21/1995		
	BI	JP	7-345689		Sumitomo Pharmaceuticals Co., Ltd.	12/07/1995		
	BJ	JP	8-103240		Sumitomo Pharmaceuticals Co., Ltd.	03/28/1996		
	BK	WO	96/11949		Amgen, Inc.	04/25/1996		
	BL	WO	96/11950		Amgen, Inc.	04/25/1996		
	BM	WO	96/11951		Amgen, Inc.	04/25/1996		
	BN	WO	96/11952		Amgen, Inc.	04/25/1996		
	BO	JP	8-214378		Sumitomo Pharmaceuticals Co., Ltd.	07/24/1996		
	BP	WO	96/22369		Amgen, Inc.	07/25/1996		
	BQ	WO	96/25422		Human Genome Sciences, Inc.	8/22/1996		
	BR	WO	97/20929		Sumitomo Pharmaceuticals Co., Ltd.	12/06/1997		
	BS	WO	98/16642		Amgen, Inc.	04/23/1998		
	BT	WO	98/16243		Amgen, Inc.	04/23/1998		
	BU	WO	98/06844		Human Genome Sciences, Inc.	02/19/1998		
	BV	GB	2 321 852 A		Rohto Pharmaceutical Co. Ltd.	08/12/1998		
	BW	JP	10-330283		Sumitomo Seiyaku Corp, Ltd.	12/15/1998		
	BX	JP	10-330284		Sumitomo Seiyaku Corp, Ltd.	12/15/1998		

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	BY	JP	10-330285		Sumitomo Seiyaku Corp, Ltd.	12/15/1998		
	BZ	WO	99/32135		Human Genome Sciences, Inc.	07/01/1999		
	CA	WO	99/41282		Human Genome Sciences, Inc.	08/19/1999		
	CB	WO	00/72872		Human Genome Sciences, Inc.	12/07/2000		
	CC	WO	00/69407		Procter & Gamble Company	11/23/2000		
	CD	WO	01/02433		Human Genome Sciences, Inc.	01/11/2001		
	CE	WO	02/077155		Human Genome Sciences, Inc.	10/03/2002		

OTHER REFERENCES - NON PATENT LITERATURE DOCUMENTS

Examiner Initials ²	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CF	BASS, S., <i>et al.</i> , "Multicopy Suppressors of Prc Mutant <i>Escherichia coli</i> Include Two HtrA (DegP) Protease Homologs (HhoAB), DksA, and a Truncated RlpA," <i>J. Bacteriol.</i> 178:1154-1161, American Society for Microbiology (1996).	
	CG	BANEYX, F. <i>et al.</i> , "In Vivo Degradation of Secreted Fusion Proteins by the <i>Escherichia coli</i> Outer Membrane Protease OmpT," <i>J. Bacteriology</i> 172(1):491-494 (1990).	
	CH	BOWIE, J.U., <i>et al.</i> , "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> 247:1306-1310, American Association for the Advancement of Science (1990).	
	CI	CHEN <i>et al.</i> , "Stabilization of recombinant human keratinocyte growth factor by osmolytes and salts", <i>J. Pharm. Sciences</i> 85(4):419-422 (1996).	
	CJ	CHEN <i>et al.</i> , "Aggregation pathway of recombinant human keratinocyte growth factor and its stabilization", <i>Pharmaceutical Research</i> 11(11):1581-1587 (1994).	
	CK	FINCH, P.W. <i>et al.</i> , "Human KGF is FGF-Related with Properties of a Paracrine Effector of Epithelial Cell Growth," <i>Science</i> 245:752-755 (1989).	
	CL	HARTUNG, H. <i>et al.</i> , "Murine FGF-12 and FGF-13: expression in embryonic nervous system, connective tissue and heart," <i>Mech. Develop.</i> 65:31-39 (June 1997).	
	CM	HARTUNG, H. <i>et al.</i> , "Assignment of <i>Fgf12</i> to mouse chromosome bands 16B1→B3 in situ hybridization," <i>Cytogenet. Cell Genet.</i> 76: 185-186 (April 1997).	
	CN	IGARASHI, M. <i>et al.</i> , "Characterization of Recombinant Human Fibroblast Growth Factor (FGF) - 10 Reveals Functional Similarities with Keratinocyte Growth Factor (FGF-7)", <i>J. Biological Chemistry</i> 273(21):13230-13235 (1998).	

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Sheet	4	of	8	Attorney Docket Number	PF155P2

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Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	CO	INNES, D., <i>et al.</i> , "The cryptic <i>ushA</i> gene (<i>ushA</i> ⁺) in natural isolates of <i>Salmonella enterica</i> (serotype Typhimurium) has been inactivated by a single missense mutation,; <i>Microbiology</i> 147: 1887-1896, Society for General Microbiology (July 2001).			
	CP	JIMENEZ, P. <i>et al.</i> , "Effect of Topical Keratinocyte Growth Factor-2 on Wound Healing in a Glucocorticoid-Impaired Model," <i>J. Cutan. Pathol.</i> 24: 105 (February 1997).			
	CQ	JIMENEZ, P.A. <i>et al.</i> , "Effect of Keratinocyte Growth Factor-2 on Cell Proliferation <i>In vivo</i> ," <i>FASEB J.</i> 11:AS23, Abstract No.3025 (April 1997).			
	CR	JIMENEZ, P.A. and Rampy, M.A., "Keratinocyte Growth Factor-2 Accelerates Wound Healing in Incisional Wounds," <i>J. Surg. Res.</i> 81:238-242, Academic Press, Inc. (February 1999).			
	CS	KELLEY, M.J. <i>et al.</i> , "Emergence of the Keratinocyte growth factor multigene family during the great ape radiation," <i>Proc. Natl. Acad. Sci. USA</i> 89:9287-9291 (1992).			
	CT	MASON, I.J. <i>et al.</i> , "FGF-7 (keratinocyte growth factor) expression during mouse development suggest roles in myogenesis, forebrain regionalization and epithelial-mesenchymal interaction," <i>Mech. Dev.</i> 45: 15-30 (1994).			
	CU	MEERMAN, H.J. <i>et al.</i> , "Construction and Characterization of a Set of E. coli Strains Deficient in All Known Loci Affecting the Proteolytic Stability of Secreted Recombinant Proteins," <i>BioTechnology</i> 12: 1107-1110 (1994).			
	CV	MIYAMOTO, M. <i>et al.</i> , "Molecular Cloning of a Novel Cytokine cDNA Encoding the Ninth Member of the Fibroblast Growth Factor Family, Which has a Unique Secretion Property," <i>Mol. Cell. Biol.</i> 13(7):4251-4259 (1993).			
	CW	NGO, J.T., <i>et al.</i> "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox," in: <i>The Protein Folding Problem and Tertiary Structure Prediction</i> , Merz, Jr., K. and Le Grand, S., eds., Birkhauser, Boston, Massachusetts, pp.491-495 (1994).			
	CX	ROBSON, B. and Garnier, J., "Modern ideas and notation relating to primary structure," in: <i>Introduction to Proteins and Protein Engineering</i> , Robson, B. and Garnier, J., eds., Elsevier Science, Amsterdam, The Netherlands, p.41 (1986).			
	CY	RON, D. <i>et al.</i> , "Expression of Biologically Active Recombinant Keratinocyte Growth Factor," <i>J. Biol. Chem.</i> 268(4):2984-2988 (1993).			
	CZ	SCOPES, R.K. "Protein Purification: Principles and Practice" (3 rd ed.) New York: Springer-Verlag (1994).			
	DA	WELLS, J.A., "Additivity of Mutational Effects in Proteins," <i>Biochem.</i> 29:8509-8519, American Chemical Society, (1990).			

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	DB	YAMASAKI, M. <i>et al.</i> , "Structure and Expression of the Rat mRNA Encoding a Novel Member of the Fibroblast Growth Factor Family," <i>J. Biol. Chem.</i> 271:15918-15921 (July 1996).	
	DC	YAN, G. <i>et al.</i> , "Sequence of Rat Keratinocyte Growth Factor (Heparin-Binding Growth Factor Type 7)," <i>In Vitro Cell. Dev. Biol.</i> 27A:437-438 (1991).	
	DD	NCBI Entrez, GenBank Report with Revision History, Accession No. M79878, McCombie, W.R. <i>et al.</i> (1992).	
	DE	NCBI Entrez, GenBank Report with Revision History, Accession No. T52063, Hillier, L. <i>et al.</i> (1995).	
	DF	NCBI Entrez, GenBank Report with Revision History, Accession No. D46201, Sasaki, T. <i>et al.</i> (1995).	
	DG	NCBI Entrez, GenBank Report with Revision History, Accession No. D46420, Sasaki, T. <i>et al.</i> (1995)	
	DH	NCBI Entrez, GenBank Report with Revision History, Accession No. D54216, Fujiwara, T. <i>et al.</i> (1995).	
	DI	NCBI Entrez, GenBank Report with Revision History, Accession No. D68729, Kohara, Y. <i>et al.</i> (1995)	
	DJ	NCBI Entrez, GenBank Report with Revision History, Accession No. D65627, Kohara, Y. <i>et al.</i> (1995)	
	DK	NCBI Entrez, GenBank Report with Revision History, Accession No. D69248, Kohara, Y. <i>et al.</i> (1995)	
	DL	NCBI Entrez, GenBank Report with Revision History, Accession No. D66221, Kohara, Y. <i>et al.</i> (1995)	
	DM	NCBI Entrez, GenBank Report with Revision History, Accession No. C02000, Okubo, K. (July 1996).	
	DN	NCBI Entrez, GenBank Report with Revision History, Accession No. W29377, Marra, M. <i>et al.</i> (September 1996).	
	DO	NCBI Entrez, GenBank Report with Revision History, Accession No. W32720, Hillier, L. <i>et al.</i> (October 1996).	
	DP	NCBI Entrez, GenBank Report with Revision History, Accession No. W60824, Hillier, L. <i>et al.</i> (October 1996).	
	DQ	NCBI Entrez, GenBank Report with Revision History, Accession No. T70682, Shen, B. <i>et al.</i> (October 1996).	
	DR	NCBI Entrez, GenBank Report with Revision History, Accession No. AA094753, Liew, C.C. (October 1996).	

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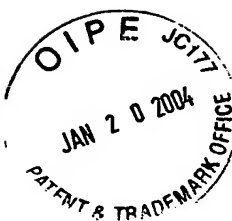
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	DS	NCBI Entrez, GenBank Report with Revision History, Accession No. AA133331, Hillier, L. <i>et al.</i> (November 1996).	
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	DU	NCBI Entrez, GenBank Report with Revision History, Accession No. AA018953, Hillier, L. <i>et al.</i> (January 1997).	
	DV	NCBI Entrez, GenBank Report with Revision History, Accession No. AA240978, Marra, M. <i>et al.</i> (March, 1997).	
	DW	NCBI Entrez, GenBank Report with Revision History, Accession No. AA289560, Marra, M. <i>et al.</i> (April 1997).	
	DX	NCBI Entrez, GenBank Report with Revision History, Accession No. AA296993, Adams, M.D. <i>et al.</i> (April 1997).	
	DY	NCBI Entrez, GenBank Report with Revision History, Accession No. AA298937, Adams, M.D. <i>et al.</i> (April 1997).	
	DZ	NCBI Entrez, GenBank Report with Revision History, Accession No. AA312184, Adams, M.D. <i>et al.</i> (April 1997).	
	EA	NCBI Entrez, GenBank Report with Revision History, Accession No. AA312483, Adams, M.D. <i>et al.</i> (April 1997).	
	EB	NCBI Entrez, GenBank Report with Revision History, Accession No. AA356781, Adams, M.D. <i>et al.</i> (April 1997).	
	EC	NCBI Entrez, GenBank Report with Revision History, Accession No. AA412789, Marra, M. <i>et al.</i> (May 1997).	
	ED	NCBI Entrez, GenBank Report with Revision History, Accession No. AA472256, Marra, M. <i>et al.</i> (June 1997).	
	EE	NCBI Entrez, GenBank Report with Revision History, Accession No. U67918, Jimenez, P.A. <i>et al.</i> , National Center for Biotechnology Information (July 1997).	
	EF	NCBI Entrez, GenBank Report with Revision History, Accession No. C38464, Kohara, Y. <i>et al.</i> (September 1997).	
	EG	NCBI Entrez, GenBank Report with Revision History, Accession No. C56505, Kohara, Y. <i>et al.</i> (September 1997).	
	EH	NCBI Entrez, GenBank Report with Revision History, Accession No. C57074, Kohara, Y. <i>et al.</i> (September 1997).	
	EI	NCBI Entrez, GenBank Report with Revision History, Accession No. C58558, Kohara, Y. <i>et al.</i> (September 1997).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/035,212-Conf. #3494
				Filing Date	January 4, 2002
				First Named Inventor	Steven Ruben
				Art Unit	1631
				Examiner Name	M. Borin
Sheet	7	of	8	Attorney Docket Number	PF155P2

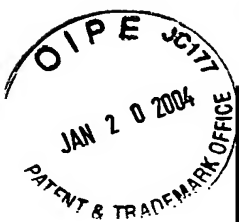
OTHER REFERENCES - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	EJ	NCBI Entrez, GenBank Report with Revision History, Accession No. C58846, Kohara, Y. <i>et al.</i> (September 1997).	
	EK	NCBI Entrez, GenBank Report with Revision History, Accession No. C59317, Kohara, Y. <i>et al.</i> (September 1997).	
	EL	NCBI Entrez, GenBank Report with Revision History, Accession No. C59311, Kohara, Y. <i>et al.</i> (September 1997).	
	EM	NCBI Entrez, GenBank Report with Revision History, Accession No. AA605609, Clark, M. <i>et al.</i> (September 1997).	
	EN	NCBI Entrez, GenBank Report with Revision History, Accession No. AA621871, NCI-CGAP (October 1997).	
	EO	NCBI Entrez, GenBank Report with Revision History, Accession No. AA621888, NCI-CGAP (October 1997).	
	EP	NCBI Entrez, GenBank Report with Revision History, Accession No. AA675470, Marra, M. <i>et al.</i> (November 1997).	
	EQ	NCBI Entrez, GenBank Report with Revision History, Accession No. AA675519, Marra, M. <i>et al.</i> (November 1997).	
	ER	NCBI Entrez, GenBank Report with Revision History, Accession No. AA838994, Marra, M. <i>et al.</i> (February 1998).	
	ES	NCBI Entrez, GenBank Report with Revision History, Accession No. H35048, Lee, N.H. <i>et al.</i> (April 1998).	
	ET	NCBI Entrez, GenBank Report with Revision History, Accession No. AA906051, NCI-CGAP (May 1998).	
	EU	NCBI Entrez, GenBank Report with Revision History, Accession No. C78836, Ko, M.S.H. <i>et al.</i> (June 1998).	
	EV	English language translation of WO 97/20929	
	EW	English language translation of JP 7-345689 (Cite No. BI)	
	EX	English language translation of JP 8-103240 (Cite No. BJ)	
	EY	English language translation of JP 8-214378 (Cite No. BO)	
	EZ	English language translation of JP 10-330283 (Cite No. BW)	
	FA	English language translation of JP 10-330284 (Cite No. BX)	
	FB	English language translation of JP 10-330285 (Cite No. BY)	
	FC	Pending Non-Provisional U.S. Patent Application No. 09/585,541, Gentz <i>et al.</i> , filed June 2, 2000.(NOT PUBLISHED)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/035,212-Conf. #3494
				Filing Date	January 4, 2002
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Sheet	8	of	8	Attorney Docket Number	PF155P2

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	FD	Pending Non-Provisional U.S. Patent Application No. 09/610,651, Ruben <i>et al.</i> , filed June 30, 2000 (NOT PUBLISHED)	
	FE	Pending Non-Provisional U.S. Application No. 10/695,957, filed June 2, 2003 (NOT PUBLISHED).	
	FF	Pending Non-Provisional U.S. Application No. 10/733,311, filed December 12, 2003 (NOT PUBLISHED).	
	FG	Pending Non-Provisional U.S. Application No. 10/461,643, filed June 16, 2003 (NOT PUBLISHED).	

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